apoplex medical technologies

G1.01.Requirement_profile

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1. Summary

1.1. Responsible

Jens Meder is the contact person for this requirement. The contact person accompanies this requirement over the entire life cycle.

1.2. Identifier

ARC-Req2_2 : Analyse ecg data

1.3. Description

1.3.1. What should be improved/solved with the requirement?

- Analyze an ecg including all available ecg channels
  - Support for multiple ECG devices
  - Detect and annotate episodes of Atrial Fibrillation (AF) and Atrial Flutter (AFl) of 30s and more
  - Detect and annotate signal noise and artefacts in each channel
  - Calculate the atrial fibrillation burden (AF Burden) in terms of
    - the longest episode of AF/AFl measured in seconds
    - the percentage of AF/AFl, e.g., 14% for a total of 42s of af in a 300s recording
  - Calculate the Heart Rate Variability (HRV) using root mean square of successive differences (RMSSD) in milliseconds
  - Calculate the signal quality in terms of net time without artefacts or signal noise
  - Calculate the heart rate (exclude noisy areas to avoid measurement errors)
  - Analysis result is uniquely identifiable (without referencing the specific patient)

1.3.2. Value

- Analysis result include following information:
  - AF was correctly detected and annotated
  - Noise was correctly detected and annotated
  - Calculated AF burden
  - Calculated HRV
  - Calculated signal quality
  - Calculated heart rate
- Authorized user can access the correct result
- Authorized user generally do not need more than 20 seconds to access the result

- The user needs maximum 3 seconds to classify the result.
- A printable document format is available.
- Notes for proposal:
    - The Analysis will have a medical purpose. This makes the following steps necessary:
        - More details will be part of the validation plan and clinical evaluation
        - Precise definition is therefore made in the corresponding process activities

1.3.3. Supported Devices

- Bittium Faros

2. Use Cases

2.1. Use Case ARC-Req2_2-Uc1 (AF)

- Personas
  - Employee in a private medical practice
  - Desktop PC of the practice
- Preconditions
  - ECG data of a patient with AF (atrial fibrillation) is recorded and available for analysis
- Procedure
  - The ECG data is provided for analysis.
- Expected result
  - The employee interprets the visualized analysis result as AF.

2.1.1. Risks

2.1.1.1. Risk ARC-Req2_2-Uc1-Risk1

2.1.1.1.1. Hazard

- False positive analysis result

2.1.1.1.2. Harm

- Further treatment due to false positive analysis is performed

2.1.1.2. Risk ARC-Req2_2-Uc1-Risk2

2.1.1.2.1. Hazard

- Incorrect assignment of the analysis report

2.1.1.2.2. Harm

- A patient with AF is not recognized

2.1.1.3. Risk ARC-Req2_2-Uc1-Risk3

2.1.1.3.1. Hazard

- Presentation of a non-representative 5-minute episode

2.1.1.3.2. Harm

- A patient with AF is not recognized and will not be treated accordingly

2.1.1.4. Risk ARC-Req2_2-Uc1-Risk4

2.1.1.4.1. Hazard

- Wrong interpretation of the analysis result due to untrained personnel

2.1.1.4.2. Harm

- A patient with AF is not recognized and will not be treated accordingly

2.1.1.5. Risk ARC-Req2_2-Uc1-Risk5

2.1.1.5.1. Hazard

- Wrong interpretation of the analysis result due to misleading presentation or unreadable analysis result

2.1.1.5.2. Harm

- A patient with AF is not recognized and will not be treated accordingly

2.2. Use Case ARC-Req2_2-Uc2 (AFL)

- Personas
    - Employee in a private medical practice
    - Desktop PC of the practice
- Preconditions
    - ECG data of a patient with AFL (atrial flutter) is recorded and available for analysis
- Procedure
    - The ECG data is provided for analysis.
- Expected result
    - The employee interprets the visualized analysis result as AFL.

2.2.1. Risks

2.2.1.1. Risk ARC-Req2_2-Uc2-Risk1

2.2.1.1.1. Hazard

- False positive analysis result

2.2.1.1.2. Harm

- Further treatment due to false positive analysis is performed

2.2.1.2. Risk ARC-Req2_2-Uc2-Risk2

2.2.1.2.1. Hazard

- Incorrect assignment of the analysis report

2.2.1.2.2. Harm

- A patient with AFL is not recognized

2.2.1.3. Risk ARC-Req2_2-Uc2-Risk3

2.2.1.3.1. Hazard

- Presentation of a non-representative 5-minute episode

2.2.1.3.2. Harm

- A patient with AFL is not recognized and will not be treated accordingly

2.2.1.4. Risk ARC-Req2_2-Uc2-Risk4

2.2.1.4.1. Hazard

- Wrong interpretation of the analysis result due to untrained personnel

2.2.1.4.2. Harm

- A patient with AFL is not recognized and will not be treated accordingly

2.2.1.5. Risk ARC-Req2_2-Uc2-Risk5

2.2.1.5.1. Hazard

- Wrong interpretation of the analysis result due to misleading presentation or unreadable analysis result

2.2.1.5.2. Harm

- A patient with AFL is not recognized and will not be treated accordingly

2.3. Use Case ARC-Req2_2-Uc3 (sinus)

- Personas
    - Employee in a private medical practice
    - Desktop PC of the practice
- Preconditions
    - ECG data of a patient with a normal sinus rhythm is recorded and available for analysis
- Procedure

    - The ECG data is provided for analysis.
- Expected result
    - The employee interprets the visualized analysis result as a normal ecg without arrhythmia.

2.3.1. Risks

2.3.1.1. Risk ARC-Req2_2-Uc3-Risk1

2.3.1.1.1. Hazard

- False negative analysis result

2.3.1.1.2. Harm

- Further treatment due to false negative analysis is performed

2.3.1.2. Risk ARC-Req2_2-Uc3-Risk2

2.3.1.2.1. Hazard

- Incorrect assignment of the analysis report

2.3.1.2.2. Harm

- A patient with sinus ecg rhythm is not recognized as such, and will be treated inapropriately.

2.3.1.3. Risk ARC-Req2_2-Uc3-Risk3

2.3.1.3.1. Hazard

- Wrong interpretation of the analysis result due to untrained personnel

2.3.1.3.2. Harm

- A patient with sinus ecg rhythm is not recognized as such, and will be treated inapropriately.

2.3.1.4. Risk ARC-Req2_2-Uc3-Risk4

2.3.1.4.1. Hazard

- Wrong interpretation of the analysis result due to misleading presentation or unreadable analysis result

2.3.1.4.2. Harm

- A patient with sinus ecg rhythm is not recognized as such, and will be treated inapropriately.

2.4. Use Case ARC-Req2_2-Uc4 (noise)

- Personas
  - Employee in a private medical practice
  - Desktop PC of the practice
- Preconditions
  - ECG data with noise of a patient is recorded and available for analysis
- Procedure
  - The ECG data is provided for analysis.
- Expected result
  - The employee interprets the visualized analysis result as a ecg with noise.

2.4.1. Risks

2.4.1.1. Risk ARC-Req2_2-Uc4-Risk1

2.4.1.1.1. Hazard

- Incorrect assignment of the analysis report

2.4.1.1.2. Harm

- A patient with AF/AFL is not recognized

2.5. Use Case ARC-Req2_2-Uc5 (no supported ecg format)

- Personas
  - Employee in a private medical practice
  - Desktop PC of the practice
- Preconditions
  - ECG data of a patient is recorded and available for analysis, however the ecg data is not supported.
- Procedure
  - The ECG data is provided for analysis.
- Expected result
  - The employee interprets the visualized analysis result as a ecg that is not supported and cannot be analysed.

2.5.1. Risks

2.5.1.1. Risk ARC-Req2_2-Uc5-Risk1

2.5.1.1.1. Hazard

No assignment of ecg data

2.5.1.1.2. Harm

A patient with AF/AFL is not recognized

Approval

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